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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,026	07/03/2000	Todd M. Boyce	285-118	3202

7590

04/23/2003

Peter Dilworth
Dilworth & Barrese LLP
333 Earle Ovington Blvd
Uniondale, NY 11553

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/23/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/610,026

Applicant(s)

BOYCE ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/03 has been entered.

Drawings

Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "tunnel, cone or tube" and also the "crescent apron for single site use, an I-shape to be placed between teeth for intra bony defects, a rectangular bib for defects involving both the buccal and lingual alveolar ridges, neutralization plates, reconstructive plates, buttress plates, T-buttress plates, a spoon plate, a clover leaf plate, a condylar plate, a compression plate, a bridge plate, a wave plate, a concave contoured plate, bowl shaped, a defect shaped plate" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objections to the drawings will not be held in abeyance.

Claim Objections

Claims 82,83 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 82 depends from claim 81, which recites "the elongate bone-derived particles are selected from the group consisting of nondemineralized bone particles, demineralized bone particles, and mixtures thereof." Claim 82 recites the same limitation and claim 83 does also which depends from claim 82.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49, 61,62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 49, how can a particle be considered elongate if there are length and width dimensions that overlap in their ranges? For example, measurements can be 2-20mm for both

the length and width which would result in non-elongate dimensions if both length and width measurements in the 2-20mm range were the same.

With respect to claim 61, it is not understood how a mixture of nondemineralized and demineralized bone particles can exist if the ratio is 0:1 or 1:0.

Regarding claim 62, it is not understood how a mixture of bone powder and elongate bone particles can exist if the ratio is 1:0.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 41-60,61 as best understood, 63-65,67,69-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowd et al. (5507813). Dowd et al. disclose the use of bone particles to make a shaped material such as a sheet or plate, col. 2, lines 20-26. Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance the recitation "about 32%" for a maximum void volume is met by Dowd since the use of "about" is broad and can reasonably be interpreted to include a variance of $\pm 5\%$. Applicant's specification confirms that the subject matter of Dowd's osteoimplant of elongate bone particles in the form of a sheet have a 37% void volume. Thus, it can be fairly said that a variance of (-) 5% results in a void volume of "about" 32%. Dowd also discloses the source of elongate particles can be from cortical, allogenic or xenogenic origin, col. 3,

lines 19-22. Regarding claims 57,81-83, the bone particles can be demineralized, col. 3, lines 26-30. The particles can be combined with one or more additives such as plasticizers and binders, col. 1, lines 48-51. Bone powder can also be added in the osteoimplant and can include demineralized bone powder, col. 4, lines 7,45,46. With respect to claims 48,78, the binder can be a polymeric bioabsorbable agent, col. 4, lines 4-6. Regarding claims 45,46,73,75, Applicant's specification confirms that the subject matter of Dowd's osteoimplant of elongate bone particles has a density "about" 0.8 g/cm^3 .

Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance the terminology of *about* (0.8 g/cm^3) for a minimum density is met by Dowd since the use of "about" is broad and the interpretation can reasonably include a variance of $\pm 0.5 \text{ g/cm}^3$. Dowd also discloses the elongate bone particles mechanically adhere to each other by entanglement or adhesives, col. 2, lines 14-17. Dowd additionally discloses the elongate bone particles have at least 60% weight possessing a median length of 2-200mm and width of 1-20mm and also a median length to median thickness ratio of 50:1 up to 500:1, col. 3, lines 1-10. A 3-D architecture can be constructed using a three-dimensional mold, col. 4, line 67. The sheet of material can be formed into a defect shaped plate or membrane (col. 5, lines 27-30) and can be used for arthroplasty, col. 5, lines 41-56. The elongate bone particles can be admixed with one or more biocompatible components such as biostatic/biocidal agents, that include antibiotics, col. 4, lines 1,11,12. Regarding claim 70, Applicant's specification

confirms that the subject matter of Dowd's osteoimplant sheet of elongate bone particles has a thickness "about" 2000 μ . Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance the terminology of *about* (2000 μ) for a maximum thickness is met by Dowd since the use of "about" is broad and it can reasonably be interpreted with a variance of $\pm 0.5\text{mm}$.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 62 as best understood is rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813. Dowd is explained supra. However, Dowd does not disclose the bone particles being mixed with a ratio up to 1:4. It would have been an obvious matter of design choice to use a weight ratio up to 1:4 with the osteoimplant of Dowd et al. since applicant has not disclosed that the weight ratios of the bone particles to bone powder as an important feature or solves any stated problem or is established for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the weight ratio of bone powder and bone particles taught by Dowd or the claimed weight ratio up to 1:4 in claim(s) 62 because both the Dowd mixture and the claimed bone powder/bone particle weight ratio up 1:4 perform the same function of reducing the porosity or void volume of the implant.

Claims 66,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. '813 in view of Boyce et al. (WO 99/39757). Dowd is explained supra. However, Dowd does not disclose the osteoimplant in laminate form or that there is at least one zone of impermeability to soft tissue ingrowth. Boyce shows an osteoimplant (Fig. 2) having a laminate form. Boyce teaches that the bone elements are crosslinked (pages 15-18) for bonding of the elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a laminate form as taught by Boyce of the Dowd osteoimplant in order to provide a thicker implant to fill a deeper defect of a patient. Some patient's may have greater bone deterioration than others, thus requiring a laminate form as opposed to a single sheet. It would have been obvious to one of ordinary skill in the art to crosslink the bone elements as taught by Boyce in the osteoimplant of Dowd in order to form a cohesive material. It is inherent that the crosslinked area would prevent soft tissue ingrowth because of the bonds formed.

Response to Arguments

Applicant's arguments with respect to new claims 41 and 77 have been considered but are moot in view of the new ground(s) of rejection.

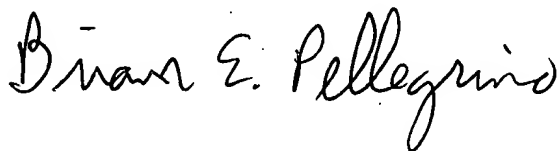
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738
April 18, 2003

A handwritten signature in cursive script that reads "Brian E. Pellegrino". The signature is written in dark ink and is positioned below the typed name and date.